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EXAMINER	
LEE, JAE W	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,295	MANTOVANI ET AL.	
	Examiner	Art Unit	
	JAE W. LEE	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02/09/2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *3 and 8-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-7 and 11-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/23/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Application status

The previous amendment to claims, filed on 02/09/2009, is acknowledged, wherein Applicants have amended claims 1, 2 and 4-7, and added claims 11-16.

Claims 1-16 are pending in this application.

Priority

The instant application is the 371 national stage entry of PCT/IT04/00745, filed on 12/21/2004. The Examiner notes that the requirements of national stage entry of the instant application had been completed (note assigned U.S. filing date) within 30 months of the earliest claimed priority date; the related international application includes both a search report and a preliminary examination report. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) to a foreign patent application RM2003A000595 (Italy) filed without English translation on 12/23/2003.

Election

Applicant's election with traverse of Group I, Claims 1, 4-7 and 11-16 in the response filed on 02/09/2009, is acknowledged.

The traversal is on the ground(s) that the Examiner has inadvertently overlooked the objective in claim 3 of improving fertility in women. Also, Applicants argue that the examination of all pending claims would not constitute a serious burden. Although the inventions identified by the Examiner are separately patentable, both the need for

compact prosecution and the public interest would be served by examination of all claims in a single application. Further, the claims of Group I are generic for the claims of Group II. If the elected claims are patentable, then also administering TSG-6 for treatment of the same bone or cartilage diseases would also be patentable.

This is not found persuasive because the shared technical feature of the groups is not a "special technical feature", unity of invention between the groups does not exist as explained in the previous office action. Contrary to Applicants' argument that Group I is generic for Group II, Group II is drawn to *compositions and use of the compositions*, and NOT to *methods* of administering the compositions to a relevant patient (emphasis added). As such, there is no genus/species relationship between Groups I and II. Furthermore, regardless of whether there is a search burden or not, there is no unity of invention between groups, and the previous restriction requirement is deemed proper. Also, claim 3 was not left out inadvertently as alleged by Applicants because it was included in Group II as shown on page 2 of the previous office action mailed on 01/09/2009. Claim 2 has been rejoined to Group I because of Applicants' amendment to claims.

Claims 3 and 8-10 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

Applicants' filing of information disclosure, filed on 06/23/2006, is acknowledged. The references that are missing have been lined through.

Claim Objections

Claims 1 and 2 are objected to because of the following informalities:

Claims 1 and 2 recite abbreviations, "PTX3" and "TSG-6", respectively without writing out what these abbreviations stand for. The Examiner suggests that Applicants write out these abbreviations in the first instance of their use followed by these abbreviations in parenthesis.

Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4-7 and 11-16 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 (4-7 and 11-16 dependent therefrom) recite the phrase, "a bone or cartilage disease unrelated to autoimmune diseases" which is unclear and indefinite. The reason is that a bone or cartilage disease, i.e., arthritis as recited in dependent claims 7, 11 and 12, is *related to autoimmune diseases involving inflammation, production of cytokines and swelling of the joint*, which is also acknowledged in the instant specification on page 4, 2nd paragraph (emphasis added). As such, it is unclear and indefinite how a bone or cartilage disease, such as arthritis, is unrelated to autoimmune diseases. In the interest of advancing prosecution, the note phrase is interpreted as "a bone or cartilage disease".

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-7 and 11-16 are rejected under 35 U.S.C. § 112, first paragraph, written description, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are directed to a genus of methods for treating a bone or cartilage disease comprising administering a PTX3 *from any source* or one of its functional derivatives including *any analogue of PTX3 having one or more mutations, deletions, insertions or post-transductional modifications while maintaining TSG-6*

binding activity, optionally in combination with TSG-6, to a patient for the preparation of a medicament for the treatment of the bone or cartilage disease (emphasis added). See above 112 2nd paragraph rejection for the claim interpretation.

To satisfy the written description aspect of 35 U.S.C. § 112, first paragraph, for a claimed genus of [compositions or methods], it must be clear that: (1) the identifying characteristics of the claimed [compositions or methods] have been disclosed, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these; and (2) a representative number of species within the genus must be disclosed.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed

correlation between function and structure, or a combination of these (paraphrased from Enzo Biochemical Inc. v. Gen-Probe Inc. (CAFC (2002) 63 USPQ2d 1609).

University of Rochester v. G.D. Searle & Co. (69 USPQ2d 1886 (2004)) specifically points to the applicability of both Lily and Enzo Biochemical to methods of using products, wherein said products lack adequate written description. While in University of Rochester v. G.D. Searle & Co. the methods were held to lack written description because not a single example of the product used in the claimed methods was described, the same analysis applies wherein the product, used in the claimed methods, must have adequate written description as noted from Enzo Biochemical (see above).

First, it is noted by the Examiner that on page 6, 4th paragraph of the specification, it is stated that a "functional derivative" means an analogue of PTX3 having one or more mutations, deletions, insertions or post-transductional modifications while maintaining the TSG-6 binding activity. As such, the scope of "PTX3 or one of its functional derivatives" is interpreted as encompassing *a PTX3 protein from any source or any analogue of PTX3 having one or more mutations, deletions, insertions or post-transductional modifications while maintaining TSG-6 binding activity.* Given this interpretation of the "PTX3 or one of its functional derivatives", the scope of claims 1, 2, 4-7 and 11-16 are so broad as to encompass a genus of methods for treating a bone or cartilage disease comprising administering *a PTX3 protein from any source or any analogue of PTX3 having one or more mutations, deletions, insertions or post-transductional modifications while maintaining TSG-6 binding activity*, optionally in

combination with TSG-6, to a patient for the preparation of a medicament for the treatment of the bone or cartilage disease (emphasis added).

However, given [A] the high level of unpredictability associated with predicting protein's function based on its structure or predicting protein's structure based on its function, [B] lack of structure-to-function correlation between [i] a PTX3 protein from any source or any analogue of PTX3 having one or more mutations, deletions, insertions or post-transductional modifications, and [ii] the TSG-6 binding activity, and [C] the limited disclosure of the specification which only discloses a single species, i.e., a method of administering a long human PTX3 protein, one of skill in the art would not have able to recognize the genus of "functional derivatives" of a PTX3 from any source having TSG-6 binding activity, from those derivatives that lack such function. In support of this notion, proteins having very different structures can have the same function (Kisselev et al, 2002), while proteins having very similar structure can have different activities (Witkowski et al, 1999; Wishart et al, 1995).

Given the lack of additional representative species of the genus of methods for treating a bone or cartilage disease comprising administering a PTX3 *from any source* or one of its functional derivatives including *any analogue of PTX3 having one or more mutations, deletions, insertions or post-transductional modifications while maintaining TSG-6 binding activity*, optionally in combination with TSG-6, to a patient for the preparation of a medicament for the treatment of the bone or cartilage disease, as encompassed by the claims, Applicants have failed to sufficiently describe the claimed

invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1, 2, 4-7 and 11-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, because the specification, while being enabling for a method for treating a bone or cartilage disease comprising administering a human long PTX3, optionally in combination with TSG-6, to a patient for the preparation of a medicament for the treatment of the bone or cartilage disease, does not reasonably provide enablement for a method for treating a bone or cartilage disease comprising administering a PTX3 *from any source* or one of its functional derivatives including *any analogue of PTX3 having one or more mutations, deletions, insertions or post-transductional modifications while maintaining TSG-6 binding activity*, optionally in combination with TSG-6, to a patient for the preparation of a medicament for the treatment of the bone or cartilage disease as encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

The Court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

The breath of the claims. Claims 1, 2, 4-7 and 11-16 are so broad as to encompass a method for treating a bone or cartilage disease comprising administering a PTX3 *from any source* or one of its functional derivatives including *any analogue of PTX3 having one or more mutations, deletions, insertions or post-transductional modifications while maintaining TSG-6 binding activity*, optionally in combination with TSG-6, to a patient for the preparation of a medicament for the treatment of the bone or cartilage disease (emphasis added). See above 112 2nd paragraph rejections for the claim interpretation. The enablement provided is not commensurate in scope with the

claim due to the extremely large number of polypeptides of unknown structure encompassed by the claim. In the instant case, the specification enables a method of administering a single species, i.e., human long PTX3.

The amount of direction or guidance presented and the existence of working examples. The specification discloses a method of administering a single polypeptide, i.e., human long PTX3, as exemplified in WO99/32516 (see page 2, 5th paragraph). However, the specification fails to provide any clue as to the structural elements required in a PTX3 *from any source* or one of its functional derivatives including *any analogue of PTX3 having one or more mutations, deletions, insertions or post-transductional modifications* for maintaining TSG-6 binding activity so that one skilled in the art can use such polypeptides as intended by Applicants, i.e., administration of such polypeptides in treatment of the bone or cartilage disease (see page 5, 2nd paragraph of the specification). No correlation between structure and function has been presented. There is no information or guidance as to which amino acid residues in the PTX3 from any source can be modified and which ones are to be conserved to create a functional derivative including *any analogue of PTX3 having one or more mutations, deletions, insertions or post-transductional modifications,* displaying the same biologically function/activity as that of the PTX, i.e., TSG-6 binding activity.

The state of prior art, the relative skill of those in the art, and the predictability or unpredictability of the art. The amino acid sequence of a polypeptide determines its structural and functional properties. While the art discloses several PTX3 proteins, neither the specification nor the art provides a correlation

between structure and such function/activity such that one of skill in the art can envision the structure of a PTX3 *from any source* or one of its functional derivatives including *any analogue of PTX3 having one or more mutations, deletions, insertions or post-transductional modifications having TSG-6 binding activity.* In addition, the art does not provide any teaching or guidance as to (1) which changes can be made to the a PTX3 *from any source* or one of its functional derivatives including *any analogue of PTX3 having one or more mutations, deletions, insertions or post-transductional modifications*, while maintaining a desired biological function/activity, i.e., TSG-6 binding activity, or (2) the general tolerance of PTX3 to structural modifications and the extent of such tolerance. The art clearly teaches that modification of a protein's amino acid sequence to obtain the desired activity without any guidance/knowledge as to which amino acids in a protein are tolerant of modification and which ones are conserved is highly unpredictable. At the time of the invention there was a high level of unpredictability associated with altering a polypeptide sequence with an expectation that the polypeptide will maintain the desired activity. For example, Branden et al. (Introduction to Protein Structure, Garland Publishing Inc., New York, page 247) teach that (1) protein engineers are frequently surprised by the range of effects caused by single mutations that they hoped would change only one specific and simple property in enzymes, (2) the often surprising results obtained by experiments where single mutations are made reveal how little is known about the rules of protein stability, and (3) the difficulties in designing *de novo* stable proteins with specific functions. In support of this notion, proteins having very different structures can have the same function (Kisselev et al,

2002), while proteins having very similar structure can have different activities (Witkowski et al, 1999; Wishart et al, 1995).

The quantity of experimentation required to practice the claimed invention based on the teachings of the specification. While methods of generating or isolating variants of a polypeptide were known in the art at the time of the invention, it was not routine in the art to screen by a trial and error process, all possible PTX3 *from any source* or one of its functional derivatives including *any analogue of PTX3 having one or more mutations, deletions, insertions or post-transductional modifications*, for those that are capable of binding TSG-6. In the absence of (1) a rational and predictable scheme for mutating, deleting, inserting or modifying post-transductionally, any residue in the polypeptide of PTX3, one of skill in the art would have to test an essentially infinite number of PTX3 proteins *from any source* or one of its functional derivatives including *any analogue of PTX3 having one or more mutations, deletions, insertions or post-transductional modifications*, for those that are capable of binding TSG-6, and to determine which ones have a desired biological function, i.e., beneficial for treating a bone or cartilage disease.

Therefore, taking into consideration the extremely broad scope of the claims, the lack of guidance, the amount of information provided, the lack of knowledge about a correlation between structure and the desired function, and the high degree of unpredictability of the prior art in regard to structural changes and their effect on function, one of ordinary skill in the art would have to go through the burden of undue experimentation in order to make and use the claimed invention. Thus, Applicant has

not provided sufficient guidance to enable one of ordinary skill in the art to make and use the invention in a manner reasonably correlated with the scope of the claims.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-7 and 11-16 are rejected under 35 U.S.C. § 102(b) as being anticipated by Mantovani et al. (WO/2002/35151, see IDS).

Claims 1, 4-7 and 11-16 are directed to a method for treating a bone or cartilage disease comprising administering PTX3 or one of its functional derivatives to a patient for the preparation of a medicament for the treatment of the bone or cartilage disease. See above 112 2nd paragraph rejection for the claim interpretation.

The reference of Mantovani et al. specifically teaches a method of administrating a therapeutical amount of human long pentraxin PTX3 or a biotinylated PTX3, i.e., a functional derivative as recited in the instant claims, to a patient suffering from arthritis, wherein said PTX3 is obtained naturally, recombinantly or synthetically (see pages 10, 15 and 16), which anticipates claims 1, 4-7 and 11-16. It is noted by the Examiner that Claim 5 is included in this rejection because it is an inherent function of the biotinylated PTX3 to bind TSG-6. Therefore, the reference of Mantovani et al. anticipates Applicants' claimed methods.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4-7 and 11-16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Mantovani et al. (WO 2002/35151, see IDS) in view of Getting et al. (Journal of Biological Chemistry, 2002, Oct. 24; 277(52): 51068-76).

Claims 1, 2, 4-7 and 11-16 are directed to a method for treating a bone or cartilage disease comprising administering PTX3 or one of its functional derivatives, optionally in combination with TSG-6, to a patient for the preparation of a medicament for the treatment of the bone or cartilage disease. See above 112 2nd paragraph rejection for the claim interpretation.

The teachings of Mantovani et al. are as described above.

Mantovani et al. do not teach a method of administrating PTX3 in combination with TSG-6.

The reference of Getting et al. teaches that TSG-6 possesses anti-inflammatory property. Getting et al. specifically teaches that TSG-6 is a potent inhibitor of neutrophil influx at the site of inflammation, and has been detected in synovial fluids and joint tissues from individuals with rheumatoid arthritis and osteoarthritis (see page 51068, right column, 2nd paragraph).

It would have been obvious for one of skill in the art to practice the method of administrating a therapeutical amount of human long pentraxin PTX3 or a biotinylated PTX3 to a patient suffering from arthritis, wherein said PTX3 is obtained naturally, recombinantly or synthetically as taught by Mantovani et al., in combination with a potent inhibitor of inflammation, TSG-6, which has been detected in synovial fluids and joint tissues from individuals with rheumatoid arthritis and osteoarthritis as taught by Getting et al. One would have been motivated to co-administer PTX3 with TSG-6 for the treatment of arthritis, which is characterized by increased cytokine production and swelling of joints due to inflammation, because TSG-6 has been implicated as a potent inhibitor of inflammation especially when present in synovial fluids and joint tissues from individuals with rheumatoid arthritis and osteoarthritis. As discussed in KSR International Co. v. Teleflex Inc., 550 U.S.--, 82 USPQ2d 1385 (2007), it is considered obvious to combine prior art elements known to be used in equivalent fields of endeavor together into a single combination. The reference clearly shows that the claimed ingredients, i.e., PTX3 and TSG-6, were known to be used in equivalent fields of endeavor, i.e., for the treatment of arthritis due to their anti-inflammatory properties; thus, it is considered obvious to combine them together. Therefore, the claimed invention is *prima facie* obvious over the combined teachings of Mantovani et al. and Getting et al.

Conclusion

Claims 1, 2, 4-7 and 11-16 are rejected for the reasons as stated above. Applicants must respond to the objections/rejections in this Office action to be fully responsive in prosecution.

The instant Office action is non-final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jae W. Lee whose telephone number is 571-272-9949. The examiner can normally be reached on M-F between 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAE W LEE/
Examiner, Art Unit 1656

/SUZANNE M. NOAKES/
Primary Examiner, Art Unit 1656